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Remarks/Arguments

Claims 1-3, 18-19, 29-30 and 33 have been amended. Claims 18 and 33 have been amended to correct the "SEQ ID NO:" format. Claims 1-3, 19, and 29-30 have been amended to clarify the length of a cycle of therapy. Claims 24-28 were previously canceled. Claims 1-23 and 29-33 are pending in this application.

Claim rejections - 35U.S.C. § 102

Claims 1-5 and 13-18 were rejected under 35 U.S.C. §102(b) as being anticipated by Webb et al. The examiner maintained the rejection stating that because the claims contained the word "comprising" it would include a cycle of therapy for 2 to 13 days, plus any additional step. The Examiner stated that the therapy of Webb comprises 2 to 13 days, plus the additional step of one day, totaling 14 days. The Examiner concluded that Webb anticipates claims 1-5 and 13-18. Applicants have amended the pertinent claims to read "consisting of" instead of "comprising." Accordingly, applicants submit that the claim amendment renders this ground of rejection moot.

The Examiner has stated that Webb teaches two cycles of therapy, each lasting 7 days for a total of 14 days. Applicants respectfully point out that the Examiner has mischaracterized the teaching of Webb. Webb does not teach two cycles of therapy each lasting 7 days for a total of 14 days. Rather, Webb teaches a one 2-week course of treatment. In other words, Webb teaches treating a human with one cycle of therapy for 14 days. On page 1137 (Methods) of the Webb reference, it states: "[a] daily subcutaneous infusion . . . was administered for 2 weeks to nine patients. . . ." Further, on page 1138, second paragraph in describing the therapy in more detail, Webb states: "One 2-week course of treatment was given. Patients were followed up for 4 weeks after the end of treatment. If there was evidence of tumor response, a second course was considered." Thus, Webb clearly does not teach two cycles of therapy where each cycle of therapy is 7 day, let alone a cycle of therapy for 2 to 13 days. At the most Webb suggests is a cycle of therapy for 14 days, possibly followed by a second cycle to be administered 4 weeks after the end of the first cycle.

It appears that the Examiner is trying to argue that each day of the treatment in Webb is a cycle of therapy. It is clear from Webb et al. that the term "course" of treatment does not mean "days." The quoted passage provided above indicates that the cycle (or course) was for 2 weeks. Webb contemplated providing another cycle/course of treatment after a 4 week rest. It is clear that Webb does not teach or suggest that the cycle of course of therapy was for 7 days. To arrive at the Examiner's conclusion that Webb teaches two cycles of 7 day treatments, one must ignore the explicit teachings and language of Webb.

Further, the Examiner's argument and interpretation is contrary to the meaning of a cycle of therapy as known and used by one skilled in the art. It is generally accepted that a cycle of therapy means that treatment will be given for a certain length of time or certain number of treatments and this total length of time is one cycle. After a cycle of therapy, the patient is allowed to rest for some length of time before another cycle of therapy is administered. Attached is a page from the American Cancer Society's web site that describes a cycle of therapy:

Chemotherapy is generally given at regular intervals called cycles. A cycle may involve one dose followed by several days or weeks without treatment. This allows normal tissues time to recover from the drug's side effects. Alternatively, doses may be given several days in a row, or every other day for several days, followed by a period of rest.

Thus, given that Webb does not teach or suggest a cycle of therapy consisting of 2 to 13 days, applicants respectfully request withdrawal of this ground of rejection.

Claim rejections under 35 U.S.C. § 103

All of the claim rejections under 35 U.S.C. § 103 relied on a combination of Webb et al. and other references. In light of the claim amendments and the arguments present above, applicants submit that Webb et al. do not teach the administration of a bcl-2 antisense oligonucleotide in one or more cycles of therapy, wherein each cycle of therapy consists of 2 to 13 days. Accordingly, the combination of Webb et al. with either

Jansen et al., Klasa et al, Tortora, Adjei et al., Foran et al., or Muren et al., do not suggest or teach the presently claimed invention. Applicants, therefore, respectfully request withdrawal of this ground of rejection.

Conclusion

Applicants submit that the claims are in condition for allowance. Although it is believed that no fees are necessary for the filing of this paper, Applicants authorize the Commissioner to charge the requisite fee for such extension as well as any other fee due or credit any overpayment arising from this communication to Deposit Account No. 11-0600. A Notice of Appeal is filed concurrently herewith. The Commissioner is authorized to charge the requisite fee for the Notice of Appeal to Deposit Account No. 11-0600.

Respectfully submitted,

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Planning Drug Doses and Schedules

Some drugs, especially those available to people without a prescription, have a fairly wide *therapeutic index*. This means that wide ranges of doses can be used effectively and safely. For example, the label on a bottle of aspirin may suggest taking 2 tablets for a mild headache. But one tablet (half the dose) will probably help many people with a mild headache.

Most chemotherapy drugs, on the other hand, have a narrow range of safe and effective doses. Taking too little of the drug will not effectively treat the cancer and taking too much may cause life-threatening side effects. For this reason, doctors must calculate chemotherapy doses very precisely.

Doses

Chemotherapy doses given to people with cancer, usually measured in milligrams (mg), are sometimes based on their body weight in kilograms (1 kilogram is 2.2 pounds). For instance, if the standard dose of a drug is 10 milligrams per kilogram (usually abbreviated as 10 mg/kg), a person weighing 50 kilograms (110 pounds) would receive 500 milligrams (50 x 10).

Chemotherapy doses are most commonly determined based on body surface area (BSA), which doctors calculate using your height and weight. Dosages for children and adults differ, even after BSA is taken into account. This is because children's bodies process drugs differently. They may have different levels of sensitivity to the drugs as well.

For similar reasons, dosages of some drugs may also be adjusted for people who are elderly, have poor nutritional status, have already taken or are currently taking other medications, have already received or are currently receiving radiation therapy, have low blood cell counts, or have liver or kidney diseases.

Schedule (Cycles)

Chemotherapy is generally given at regular intervals called cycles. A cycle may involve one dose followed by several days or weeks without treatment. This allows normal tissues time to recover from the drug's side effects. Alternatively, doses may be given several days in a row, or every other day for several days, followed by a period of rest. Some drugs work best when given continuously over several days.

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If more than one drug is used, the treatment plan will specify how often and exactly when each drug should be given. The number of cycles you receive may be determined before treatment starts (based on the type and stage of cancer) or may be flexible, in order to take into account how quickly the tumor is shrinking.

Certain serious side effects may also require doctors to adjust chemotherapy plans (dosage or schedule) to allow you time to recover.

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